UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CIVIL ACTION NO. 09-12176-RGS

UNITED STATES OF AMERICA,
ex rel. DAVID PROVUNCHER

v.

ANGIOSCORE, INC.

MEMORANDUM AND ORDER ON DEFENDANT'S MOTION TO DISMISS AND RELATOR'S MOTION FOR LEAVE TO FILE A SECOND AMENDED COMPLAINT

May 1, 2012

STEARNS, D.J.

On December 22, 2009, plaintiff/relator David Provuncher, a medical device sales professional formerly employed by Angioscore, Inc., brought this action under the federal False Claims Act (FCA), 31 U.S.C. § 3729 (a)(1)(A)-(B). Provuncher alleges that AngioScore violated the FCA (Counts I and II), subjected him to a retaliatory termination in violation of 31 U.S.C. § 3730(h) (Count III), and wrongfully terminated him in violation of Massachusetts public policy (Count IV). Presently before the court are defendant's motion to dismiss and relator's motion for leave to file a Second Amended Complaint. The court heard oral argument on March 30, 2012.

BACKGROUND

Defendant AngioScore is a biotechnology firm that manufactures and distributes angioplasty catheters under the trade name AngioSculpt. Am. Compl. ¶ 21.[1] Plaintiff/relator David Provuncher, a former Senior Territory Manager for AngioScore, resides in Franklin, Massachusetts. *Id*. ¶¶ 9-10. In early 2009, AngioScore began marketing the AngioSculpt EX PTCA Scoring Balloon Catheter (EX Catheter) in the United States. *Id*. ¶¶ 4, 26, 28.[2] The Amended Complaint alleges that a design defect causes the EX Catheter to separate while in use, *id*. ¶¶ 26-27, and that AngioScore began receiving complaints about the device shortly after its introduction. By June of 2009, at least five instances of EX Catheter separation had occurred. In at least one of these incidents, a piece of the catheter was left in the patient's coronary artery. *Id*. ¶ 31.

On June 4, 2009, AngioScore sent a "Dear Doctor" letter to physicians whose hospitals had ordered the EX Catheter, stating that the letter was to "inform [them] about a rare device malfunction that has recently been reported" involving the EX

[1] AngioScore is a Delaware corporation with a principal place of business in Fremont, California. AngioScore regularly sells products in the Commonwealth of Massachusetts and maintains full-time employees within the Commonwealth. *Id*. ¶ 11.

[2] Provuncher alleges that "[n]o clinical trials in the United States were ever conducted with the EX Catheter, and only a handful of persons outside the United States were tested with the device before it was marketed here." *Id*. ¶ 28.

Catheter. *Id*.-Ex. A ("Dear Doctor" letter). By October of 2009, at least ten additional instances of EX Catheter separation had occurred. *Id*. ¶ 41. On October 8, 2009, AngioScore directed all members of its sales force to turn in their "trunk stock" of EX Catheters manufactured prior to June of 2009. In addition, AngioScore instructed its sales staff to return all consignment EX Catheters that had been given to customers on a trial basis. *Id*. ¶ 42.

The Amended Complaint alleges that "[t]he return of the trunk stock was a stealth recall designed to avoid the FDA," and that "AngioScore made no effort to recover the older units from its customers because it was afraid any such action would scare off future sales." *Id*. ¶ 43. Even after the "stealth recall," EX Catheter separation and prolapse incidents continued to occur. *Id*. ¶ 44. Provuncher "decided that he would no longer take any action to sell unsafe devices and would continue to advocate within the company that the defective devices should be taken off the market." *Id*. ¶ 54. On November 23, 2009, Provuncher contacted the FDA "to inform it of the dangers of the EX Catheter and that the company had effectuated a partial recall of pre-June 2009 catheters without informing the FDA of its actions and the reasons for taking such steps." *Id*. ¶ 55. On December 4, 2009, AngioScore announced that it was initiating a Class 2 Recall of all EX Catheters that had been manufactured prior to June

of 2009.[3] On the same day, Frank Viano, the Senior Sales Director at AngioScore, "informed [Provuncher] that he could no longer work for AngioScore." *Id.* ¶ 59.

On December 22, 2009, Provuncher filed a Complaint against AngioScore alleging violations of the FCA (Counts I and II), retaliatory termination in violation of 31 U.S.C. § 3730(h) (Count III), and wrongful termination in violation of Massachusetts public policy (Count IV). On March 7, 2011, the United States government declined to intervene. On August 12, 2011, Provuncher filed an Amended Complaint. On September 15, 2011, AngioScore filed a motion to dismiss the Amended Complaint pursuant to Rules 9(b) and 12(b)(6) of the Federal Rules of Civil Procedure. On November 23, 2011, Provuncher filed a motion for leave to file a Second Amended Complaint. The court entered an Order reserving a ruling on this motion until after it had the opportunity to hear the parties on the Motion to Dismiss. *See* Nov. 30, 2011 Order. On December 27, 2011, the government filed a "statement of interest" as to AngioScore's motion to dismiss. On January 11, 2012, AngioScore

[3] The Amended Complaint alleges that "AngioScore was aware of the defective nature of the EX Catheter long before the December 2009 recall," and that it "deliberately failed to report many of [the adverse events resulting from defects in the device] to the FDA." *Id.* ¶ 5. "When the reporting violations described in [the original Complaint] were brought to the attention of the FDA, it audited AngioScore's adverse event reporting. It determined that the program was deficient, and after reviewing the true incidence of product failure, unilaterally reclassified the EX Catheter recall as a Class 1 recall, the most serious class of recall." *Id.* ¶ 71.

filed a response.[4]

DISCUSSION

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (internal quotation omitted). "When there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief." *Id*. at 679. In *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), the Supreme Court explained that "[w]hile a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff's obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Id*. at 555 (internal citations

[4] Although the government declined to intervene in this action, it filed a statement of interest "in order to clarify that conduct such as concealing from the FDA information that would have been material to the agency's decision as to whether to approve or withdraw an approval or cause a recall of a medical device may be material to the federal healthcare programs' decision to pay claims for that device and, thus, may be actionable under the False Claims Act." Gov.'s Statement of Interest at 3. AngioScore argues that "because Relator's Amended Complaint does not present any plausible claim of fraudulent inducement based on a failure to disclose information material to the product's FDA approval, the concerns expressed in the [government's statement of interest] have no application to this case." Def.'s Resp. to Gov.'s Statement of Interest at 3.

and quotations omitted).

I. The FCA Claims

"FCA liability attaches to any individual who 'knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval,' 31 U.S.C. § 3729(a)(1)(A), or 'knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim,' *id*. § 3729(a)(1)(B)." *United States ex rel. Hutcheson v. Blackstone Med., Inc.*, 647 F.3d 377, 380 n.3 (1st Cir. 2011). "For purposes of both subsections, '[a] person acts 'knowingly' if he or she '(1) had actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information.'" *United States ex rel. Dyer v. Raytheon Co.*, 2011 WL 3294489, at *6 (D. Mass. July 29, 2011), quoting *Hutcheson*, 647 F.3d at 380; *see also Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662, 672-673 (2008) (the elements of an FCA claim require proof that a defendant knew, as a "natural, ordinary and reasonable consequence[]" of its acts, that false claims would be submitted to the government for payment).

It is well established that the heightened pleading requirements of Fed. R. Civ. P. 9(b) apply to claims brought under both subsections of the FCA. *United States ex rel. Gagne v. City of Worcester*, 565 F.3d 40, 45 (1st Cir. 2009). Although Rule 9(b)

may be satisfied where "some questions remain unanswered [but] the complaint as a whole is sufficiently particular to pass muster under the FCA," *id.*, quoting *United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 732 (1st Cir. 2007), "*Karvelas* requires the complaint to provide, among other fraud specifics, 'details concerning the dates of the claims, the content of the forms or bills submitted, their identification numbers, [and] the amount of money charged to the government.'" *Gagne*, 565 F.3d at 46, quoting *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 233 (1st Cir. 2004). AngioScore argues that Provuncher has failed to plead his FCA claims with the requisite particularity. The court agrees.

For Provuncher to make out his subsection (a)(1)(A) claim, he must show that a false claim was actually presented to the government. *See Gagne*, 565 F.3d at 44-46, citing *Allison Engine*, 553 U.S. at 669-671. Provuncher has not alleged any particulars regarding the "presentment" of any specific claim to the government. Provuncher argues that

> [a]lthough he cannot be expected to identify the specific federal claims submitted by hospitals for angioplasties performed with the EX Catheter, he does identify numerous hospitals which submitted federal claims for such procedures, where those hospitals are located and the time periods during which the claims were submitted. Relator provides the names of some of the physicians who ordered the devices.

Pl.'s Opp'n at 12, citing Am. Compl. ¶¶ 37, 49, 67.

The Amended Complaint further alleges that the vast majority of EX Catheters manufactured before June of 2009 were used in angioplasty procedures, and that "[m]ore than half of the angioplasties involving these units were paid for by the federal government through Medicare or another federally funded health care program." Am. Compl. ¶ 60. Provuncher maintains that "[w]hen a complaint alleges that the federal government pays a significant percentage of all claims for a particular drug or procedure, a relator has satisfied his burden of demonstrating that it is likely the government paid false claims." Pl.'s Opp'n at 13, citing *Rost*, 507 F.3d at 732. Provuncher also relies on *United States ex rel. Duxbury v. Ortho Biotech Products, L.P.*, 579 F.3d 13, 29-30 (1st Cir. 2009), for the proposition that "[w]here Relator has alleged the existence of a nationwide scheme to present false claims to the government, Rule 9(b) is satisfied when the Relator provides the specifics relating to representative transactions." Pl.'s Opp'n at 14, citing *Duxbury*, 579 F.3d at 31. However, even under this "'more flexible standard,'" *Duxbury*, 579 F.3d at 30, Provuncher's subsection (a)(1)(A) cause of action fails because the Amended Complaint does not allege the representative transactions with particularity.

With respect to Provuncher's subsection (a)(1)(B) claim, his footing is no more firm. Provuncher "alleges that AngioScore made numerous false statements that caused hospitals to purchase EX Catheters that were subsequently billed to federal programs."

Pl.'s Opp'n at 11. In *Gagne*, the First Circuit explained that the relator had failed to successfully plead a subsection (a)(1)(B) claim where it was simply alleged that defendants had falsified and submitted fraudulent time sheets that were eventually used to create invoices submitted for payment. *See* 565 F.3d at 47-48 ("[A] conclusory allegation that defendants' submissions of time sheets was the making or usage of a false record or statement to get a false or fraudulent claim paid or approved by the government, absent more detail about those submissions and their connection to the false or fraudulent claims, is insufficient under Rule 9(b)."). Provuncher's Amended Complaint lacks these same details. He fails to establish a tangible connection between the purported false statements and the making of false or fraudulent claims.

Provuncher alleges that "AngioScore has made numerous false statements regarding the safety of the EX Catheter," many of which appear in the June 2009 "Dear Doctor" letter and the December 2009 voluntary recall notice. Am. Compl. ¶ 68. He further alleges that "[s]ales representatives were also trained to, and did in fact, make such false statements." *Id*.; s*ee also* Pl.'s Opp'n at 11. However, these false statements involved the marketing of the catheter, *see id*. at 9 n.9; Provuncher does not connect any purportedly false statement to a specific claim that was submitted to the government. Essential facts are lacking, such as when the government was billed, what agency was billed, for how much, for what services, and whether the claim was

ultimately paid.

Thus, Provuncher has not shown how AngioScore's conduct falls within the ambit of subsection (a)(1)(B) of the FCA. While the purpose of subsection (a)(1)(B) is to bring under the FCA individuals who induce others to submit false claims to the government, it is construed more narrowly than subsection (a)(1)(A). *See United States ex rel. Totten v. Bombardier Corp.*, 380 F.3d 488, 498, 501 (D.C. Cir. 2004) ("[Subsection] (a)(2) is complementary to (a)(1), [and is] designed to prevent those who make false records or statements to get claims paid or approved from escaping liability solely on the ground that they did not *themselves* present a claim for payment or approval.").[5] The FCA, when properly deployed, is a piece of heavy artillery in the war against fraud on the government. It is not, however, intended to serve as a general purpose anti-fraud statute or as a vehicle for employee grievances. *See Hopper v. Solvay Pharm., Inc.*, 588 F.3d 1318, 1328 (11th Cir. 2009).[6]

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[5] "In 2009, Congress passed the Fraud Enforcement Recovery Act (FERA), Pub. L. No. 111–21, 123 Stat. 1617 (2009), which amended the FCA and re-designated § 3729(a)(1) as § 3729(a)(1)(A), § 3729(a)(2) as § 3729(a)(1)(B), and § 3729(b) as § 3729(b)(1)(A) & (B)." *Hutcheson*, 647 F.3d at 380 n.3. Provuncher's Amended Complaint cites to the re-designated FCA provisions.

[6] The present case is distinguishable from *New York v. Amgen, Inc.*, 652 F.3d 103 (1st Cir. 2011), and *Hutcheson*, 647 F.3d 377. In those cases, the First Circuit held that plaintiffs' subsection (a)(2) claims survived motions to dismiss where defendants knowingly caused false claims to be submitted for payment, and where the "falsity" of the claim was demonstrated by a showing that the submitted claims

On November 23, 2011, Provuncher filed an assented-to conditional motion for leave to file a Second Amended Complaint, in the event that the court finds that the Amended Complaint does not satisfy Rule 9(b).[7] He states that the proposed Second Amended Complaint addresses the pleading deficiencies raised by AngioScore. For example, the Second Amended Complaint provides "specific allegations concerning claims directly submitted to the government through Veterans Administration hospitals and military hospitals." Pl.'s Mem. in Support of Motion for Leave at 3, citing Second Am. Compl. ¶¶ 6, 18, 38, 71, Ex. C.

"Leave to amend is to be 'freely given,' Fed. R. Civ. P. 15(a), unless it would be futile, or reward, inter alia, undue or intended delay." *Resolution Trust Corp. v. Gold*, 30 F.3d 251, 253 (1st Cir. 1994) (citations omitted). AngioScore does not argue that granting Provuncher leave to file the Second Amended Complaint would be futile

misrepresented compliance with a material precondition of payment. At issue here, by contrast, is plaintiff's failure to meet the specificity requirements of Rule 9(b). In both *Amgen* and *Hutcheson*, the First Circuit declined to address defendants' Rule 9(b) arguments where they had not been considered by the district court. *See Amgen*, 652 F.3d at 111 n.7; *Hutcheson*, 647 F.3d at 384 n.8.

[7] In its statement of interest, the government notes that it "takes no position as to whether relator sets forth allegations sufficient to satisfy Rule 9(b), but, in the event of a dismissal on this basis, such a dismissal should be without prejudice to the United States." Gov.'s Statement of Interest at 3.

or would reward undue or intended delay.[8] Thus, the court will grant the motion for leave to file a Second Amended Complaint.

II. Federal Retaliation Claim

The Amended Complaint alleges that Provuncher "was terminated and discriminated against because of lawful acts he took to stop violations of the False Claims Act, to prevent harm to patients and to enforce other public policies." *Id*. ¶ 62. To prevail on a claim for retaliation under the FCA, Provuncher must show that: (1) he engaged in conduct protected under the FCA; (2) AngioScore knew that he was engaged in such conduct; and (3) AngioScore discharged him because of his involvement in the protected conduct. *See Karvelas*, 360 F.3d at 235; *United States ex rel. Cafasso v. Gen. Dynamics C4 Sys., Inc.*, 637 F.3d 1047, 1060 (9th Cir. 2011). A retaliation claim may survive even if the whistleblower claim on which it is based does not. *See Graham Cnty. Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 545 U.S. 409, 416 (2005) ("A retaliation plaintiff, instead, need prove only that the defendant retaliated against him for engaging in 'lawful acts done . . . in furtherance of' an FCA 'action filed or to be filed,' [*see* 31 U.S.C.] § 3730(h), language that protects an employee's conduct even if the target of an investigation or action to be

[8] At the hearing, counsel for AngioScore confirmed that they do not oppose the motion for leave to file a Second Amended Complaint.

filed was innocent."). Moreover, the heightened pleading requirements of Rule 9(b) do not apply to a retaliation claim based on an FCA violation. *See Karvelas*, 360 F.3d at 238 n.23.

Protected conduct in an FCA-retaliation context is interpreted broadly. *See United States ex. rel. Gobble v. Forest Labs., Inc.*, 729 F. Supp. 2d 446, 449 (D. Mass. 2010), citing *Karvelas*, 360 F.3d at 237. Protected conduct includes "activities that 'reasonably could lead' to an FCA action; in other words, investigations, inquiries, testimonies or other activities that concern the employer's knowing submission of false or fraudulent claims for payment to the government." *Karvelas*, 360 F.3d at 237 (citation omitted). "A plaintiff, however, need not have known that his actions could lead to a qui tam suit under the FCA, or even that a False Claims Act existed, in order to demonstrate that he engaged in protected conduct." *Gobble*, 729 F. Supp. 2d at 449, citing *Karvelas*, 360 F.3d at 237. The employee must, however, be actually engaged in investigating matters that at least reasonably could lead to an FCA action. *See United States ex. rel. Hopper v. Anton*, 91 F.3d 1261, 1269 (9th Cir. 1996).

AngioScore contends that Provuncher has not alleged facts sufficient to show that he had engaged in protected conduct because his investigative focus was on the safety of the EX Catheter and whether AngioScore was properly reporting adverse events, rather than on losses of money by the government. Provuncher, for his part, argues that

"[b]y complaining to his superior that the EX Catheter was unsafe, [he] was trying to stop further violations of the FCA caused by the sale and reimbursement of the misbranded catheter." Pl.'s Opp'n at 16. While this is pretty thin gruel, it arguably has enough grit to support the inference that Provuncher's inquiry was, at least potentially, motivated by a desire to protect the public fisc. *See Gobble*, 729 F. Supp. 2d at 450 (protected conduct element met where relator made inquiries about conduct actionable under the FCA in addition to inquiries about nonactionable regulatory violations).

Next, Provuncher must show that AngioScore knew that he was engaged in conduct that was protected under the FCA. "The defendants' requisite awareness 'mirrors the kind of protected activity in which an employee must be engaged.'" *Id*. at 451, quoting *Karvelas*, 360 F.3d at 238. Provuncher's Amended Complaint alleges that he spoke to several AngioScore employees, including his supervisor, Frank Viano, and AngioScore's regulatory compliance department, regarding his concerns about the safety of the EX Catheter. *See, e.g.*, Am. Compl. ¶¶ 53, 56. The Amended Complaint also alleges that Provuncher "told Viano that to continue to sell the device was to defraud the United States." *Id*. ¶ 55.

Provuncher, however, must surmount a third hurdle – he must show that his termination resulted from engaging in protected conduct. Provuncher notes that

> AngioScore proffers a non-retaliatory ground for terminating [him] – his

> refusal to sell one of the products in AngioScore's line – but even when there are other possible reasons for the termination of an employee, a complaint states an FCA retaliation claim if one of the possible reasons for dismissal was the exercise of protected conduct.

Pl.'s Opp'n at 18, citing *United States ex. rel. Nowak v. Medtronic, Inc.*, 2011 WL 3208007, at *25 (D. Mass. July 27, 2011) (stating that "[t]he inferences are sufficient, at this stage in the case, to constitute an adequate pleading that [defendant] fired [relator] 'at least in part' because of her 'protected activity.'"). Provuncher further argues that the Amended Complaint contains "allegations that raise an inference that AngioScore's claimed basis for dismissal was a pretext."[9] Pl.'s Opp'n at 18 n.19. For example, the Amended Complaint states that "[r]elator did not sell many EX Catheters, but he remained one of AngioScore's top sales representatives due to his ability to sell the other AngioScore products." Am. Compl. ¶ 51. The Amended Complaint also alleges that Provuncher "had signed on more hospitals and new physicians than most other sales representatives." *Id.* ¶ 57.

Provuncher acknowledges that he was "terminated . . . solely because he refused to promote the misbranded EX Catheters." *Id*. ¶ 85. Indeed, the record supports this

[9] Pretext is a concept derived from the burden-shifting paradigm applied in Title VII disparate treatment cases. It has only marginal relevance here, where the truthfulness of AngioScore's explanation of why Provuncher was terminated is not a determinative issue. Because Provuncher's employment was at-will, AngioScore had the right to fire him for any reason that did not offend the FCA (or public policy) and had no obligation to give Provuncher or anyone else an explanation for its decision.

conclusion. Between September of 2009 and December of 2009, Provuncher and his supervisor, Frank Viano, "had a dozen conversations" relating to Provuncher's low EX Catheter sales. *Id*. ¶ 55. In one of these conversations, Viano "threatened to replace [Provuncher] with another sales representative if he did not promote the EX Catheter," and told him that if he "did not want to sell the EX Catheter, he should be doing something else." *Id*. ¶ 57. Moreover, it is undisputed that the decision-makers at AngioScore were unaware of the fact that Provuncher had contacted the FDA when they terminated his employment. Thus, Provuncher's Amended Complaint fails to plead a causal connection between AngioScore's decision to terminate his employment and its knowledge or perception that he was engaged in protected FCA-related activity.

III. Wrongful Termination

"The general rule is that an employment-at-will contract can be terminated at any time for any reason or for no reason at all." *Folmsbee v. Tech Tool Grinding & Supply, Inc.*, 417 Mass. 388, 394 (1994), citing *Gram v. Liberty Mut. Ins. Co.*, 384 Mass. 659, 668 n.6 (1981). However, "[a]s an exception to the general rule that an employer may terminate an at-will employee at any time with or without cause, [the Supreme Judicial Court has] recognized that an at-will employee has a cause of action for wrongful termination only if the termination violates a clearly established public policy." *King v. Driscoll*, 418 Mass. 576, 582 (1994), citing *Flesner v. Technical Commc'ns Corp.*,

410 Mass. 805, 810-811 (1991). Circumstances in which termination violates an established public policy generally include discharge for "'asserting a legally guaranteed right (e.g., filing workers' compensation claim), for doing what the law requires (e.g., serving on a jury), or for refusing to do what the law forbids (e.g., committing perjury).'" *Folmsbee*, 417 Mass. at 394, quoting *Smith-Pfeffer v. Superintendent of the Walter E. Fernald State Sch.*, 404 Mass. 145, 149-150 (1989). "[The Supreme Judicial Court] consistently has interpreted the public policy exception narrowly, reasoning that to do otherwise would 'convert the general rule . . . into a rule that requires just cause to terminate an at-will employee.'" *King*, 418 Mass. at 582, quoting *Smith-Pfeffer*, 404 Mass. at 150.

AngioScore argues that the common law does not authorize claims for wrongful termination in violation of public policy where a plaintiff has a statutorily-created means of vindicating the policy at issue. AngioScore contends that the FCA "provides a comprehensive and adequate remedial scheme" for addressing alleged retaliation against whistleblowers. Pl.'s Reply at 14, citing *Fauci v. Genentech, Inc.*, 2007 WL 3020191, at *4 (D. Mass. Oct. 12, 2007). Provuncher, for his part, argues that

> [h]ere, there is no particular statute that provides a remedy for all of the conduct for which Relator seeks protection. While Relator's efforts to stop financial fraud on the United States have given rise to a [31 U.S.C. § 3730] subsection (h) retaliation claim, his efforts to stop and unwillingness to participate in violations of a public safety law, the [Food,

> Drug, and Cosmetic Act (FDCA)], give rise to his state retaliation claim. The FDCA does not provide a retaliation remedy and consequently Relator's whistleblowing under that statute can only be protected by a common law wrongful termination claim.

Pl.'s Opp'n at 20.

It would seem that investigating fraud on a government agency is the very type of activity that the public policy exception to the at-will employment rule is designed to protect. *Cf. Korb v. Raytheon Corp.*, 410 Mass. 581, 584 n.3 (1991) (although plaintiff advocated publicly against war spending, his at-will termination by his defense contractor employer was not unlawful as defendant was "not attempting to suppress [plaintiff's] speech in order to cover up its own wrongdoing."). However, a complaint about internal corporate matters – here, a disagreement by Provuncher with the decision to market the EX Catheter despite his personal reservations about the safety of doing so – does not implicate the public policy exception. *See Dorman v. Norton Co.*, 64 Mass. App. Ct. 1, 10-11 (2005).[10]

[10] There may be a public policy rationale for protecting employees who try to warn of potential harm caused by a defective product. However, Provuncher has failed demonstrate that the EX Catheter was indeed defective. As AngioScore notes, the "FDA approved the EX Catheter for use in treating artery-blocking lesions; it agreed with the limited scope of AngioScore's recall; it chose not to suspend or withdraw FDA approval for the device; and it continues to approve PMA Supplements permitting AngioScore to market the EX Catheter." Def.'s Reply at 6. AngioScore further argues that "the Supreme Court has specifically warned against allowing private citizens to circumvent FDA's exclusive authority. In *Buckman*, the Court held that state law claims were preempted because they interfered with FDA's exclusive authority 'to

ORDER

For the foregoing reasons, defendant's motion to dismiss Provuncher's Amended Complaint is ALLOWED without prejudice.[11] Provuncher's motion for leave to file a Second Amended Complaint is ALLOWED.

SO ORDERED.

/s/ Richard G. Stearns

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UNITED STATES DISTRICT JUDGE

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punish and deter fraud' and to 'balance' various objectives." Def.'s Mem. at 9, quoting *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001). AngioScore contends that "courts have applied the principles articulated in *Buckman* to bar federal statutory claims brought by private parties seeking to usurp FDA's authority." Def.'s Reply at 8. This is an issue that will arise again should Provuncher replead the wrongful termination claim in his Second Amended Complaint, and is one that deserves further briefing.

[11] On March 7, 2011, this court issued an Order stating that "should Relator or Defendants propose that this action be dismissed, settled, or otherwise discontinued, the court will solicit the written consent of the United States before ruling or granting its approval." Mar. 7, 2011 Order ¶ 7.